

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-092

CHEMISTRY REVIEW(S)

OCT 29 1999

NDA 21-092 Metabolic Solutions, Inc. Helicosol

1 of 56

DIVISION OF MEDICAL IMAGING AND RADIOPHARMACEUTICAL DRUG
PRODUCTS

Review of Chemistry, Manufacturing, and Controls

NDA #: 21-092DATE REVIEWED: October 7, 1999

Date Revised: October 28, 1999

REVIEW #: 1REVIEWER: Ravi S. Harapanhalli, Ph.D.

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	17-MAR-99	22-MAR-99	24-MAR-99
AMENDMENT (BM)	05-MAY-99	06-MAY-99	06-MAY-99
AMENDMENT (BC)	07-JUN-99	08-JUN-99	08-JUN-99
AMENDMENT (BC)	26-AUG-99	27-AUG-99	27-AUG-99

NAME & ADDRESS OF APPLICANT:Metabolic Solutions, Inc.
460 Amherst Street
Nashua, NH 03063
Contact: David A. Wagner, Ph.D.;
603-598-6960DRUG PRODUCT NAMEProprietary:

Helicosol™

Established:¹³C-Urea, 99%Code Name/#:

None

Chem.Type/Ther.Class:

Diagnostic

PHARMACOL. CATEGORY/INDICATION:Diagnostic for detecting pyloric
infection in adults.DOSAGE FORM:

Lyophilized powder

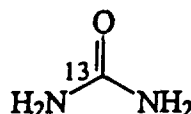
STRENGTHS:

125 mg/1 ml sterile water

POTENCY(IES)

ROUTE OF ADMINISTRATION:

Oral

Rx/OTC:☒ Rx ☐ OTCSPECIAL PRODUCTS:☐ Yes ☒ NoCHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,
MOLECULAR WEIGHT:Carbamide, Carbonyldiamine
Molecular Formula: ¹³CH₄N₂O
Molecular Weight: 61.06

SUPPORTING DOCUMENTS:

Type/Number	Subject	Holder	Status	Review Date	Evaluation
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RELATED DOCUMENTS (if applicable):

NDA	Title	Sponsor	Drug substance/Indications
20586	Pranactin®	Meretek	C-13 Urea. Diagnostic for detecting pyloric infection in adults.
20900	Pylori-Check Breath test kit	Alimenterics Inc.	C-13 Urea. Diagnostic for detecting pyloric infection in adults.

CONSULTS: The Labeling and Nomenclature committee was consulted for acceptability of the trademark "Helicosol." This was forwarded to OPDRA. However, the response from the committee is awaited.

REMARKS:

The drug substance, C-13 urea is procured from [] which is also the supplier of the drug substance []. The DMF of [] was previously found adequate to support [] NDA. The amended DMF was reviewed and found adequate to support the manufacture of bulk drug substance, C-13 urea, hence the current NDA. [] were also found adequate to support the proposed container closure system.

CONCLUSIONS & RECOMMENDATIONS:

The application is approvable pending satisfactory resolution of the deficiencies noted at the end of this review, and upon satisfactory inspections of the facilities, and acceptance of the trademark "Helicosol" by the Labeling and Nomenclature committee and OPDRA.

/S/ 2/28/99
Ravi S. Harpanhalli, Ph.D.,
Review Chemist; HFD-160/820

/S/

1/19/99

54 page(s) have been
removed because it
contains trade secret
and/or confidential
information that is not
disclosable.

HFD-590/
J. Fritsch

DEC 10 1999

**DIVISION OF MEDICAL IMAGING AND RADIOPHARMACEUTICAL DRUG
PRODUCTS**

Review of Chemistry, Manufacturing, and Controls

NDA #: 21-092

DATE REVIEWED: December 03, 1999

REVIEW #: 2

REVIEWER: Ravi S. Harapanhalli, Ph.D.

SUBMISSION TYPE **DOCUMENT DATE** **CDER DATE** **ASSIGNED DATE**

AMENDMENT (BC) 16-NOV-99

17-NOV-99

17-NOV-99

NAME & ADDRESS OF APPLICANT:

Metabolic Solutions, Inc.
460 Amherst Street
Nashua, NH 03063
Contact: David A. Wagner, Ph.D.;
603-598-6960

DRUG PRODUCT NAME

Proprietary:

Helicosol™

Established:

¹³C-Urea, 99%

Code Name/#:

None

Chem. Type/Ther. Class:

Diagnostic

PHARMACOL. CATEGORY/INDICATION:

Diagnostic for detecting pyloric
infection in adults.

DOSAGE FORM:

Lyophilized powder

STRENGTHS: 125 mg/1 ml sterile water

POTENCY(IES)

ROUTE OF ADMINISTRATION:

Oral

Rx/OTC:

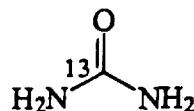
X Rx OTC

SPECIAL PRODUCTS:

 Yes X No

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,
MOLECULAR WEIGHT:**

Carbamide, Carbonyldiamine
Molecular Formula: ¹³CH₄N₂O
Molecular Weight: 61.06



SUPPORTING DOCUMENTS:

Type/Number	Subject	Holder	Status	Review Date	Evaluation
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RELATED DOCUMENTS (if applicable):

NDA	Title	Sponsor	Drug substance/Indications
20586	Pranactin®	Meretek	C-13 Urea. Diagnostic for detecting pyloric infection in adults.
20900	Pylori-Check Breath test kit	Alimenterics Inc.	C-13 Urea. Diagnostic for detecting pyloric infection in adults.

CONSULTS: The Labeling and Nomenclature committee was consulted for acceptability of the trademark "Helicosol" and was forwarded to OPDRA. In its letter dated November 2, 1999 OPDRA accepted the trade mark name "Helicosol™".

REMARKS:

The sponsor responded to the list of CMC deficiencies and their responses were found adequate to assure the product quality at release and through stability. Four facilities involved in the manufacture and release of Helicosol, [redacted] [redacted] Metabolic Solutions were inspected and were found acceptable by the Office of Compliance (OC). The overall recommendation of the OC, dated November 23, 1999 is "acceptable."

CONCLUSIONS & RECOMMENDATIONS:

From CMC perspective, the NDA is recommended for approval. The two recommendations listed at the end should be included in the action letter.

/S/

4/03/99

Ravi S. Harapanhalli, Ph.D.,
Review Chemist, HFD-160/820

cc:
Org. NDA 21092
HFD-590/NDA21092/Division File

/S/

12/10/99

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